IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Serial No.	:	**10/783,897**
Filed	:	February 20, 2004
Applicants	:	John T. Santini Jr., et al.
Title	:	Medical Device with Controlled Reservoir Opening
TC/AU	:	3763
Examiner	:	Vu, Quynh-Nhu Hoang
Docket No.	:	17648-0027
Customer No.	:	29052

REPLY BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. § 41.41, Appellants submit this Reply Brief in response to the Examiner's Answer mailed November 12, 2008, in Appellants' appeal of the final rejection of claims pending in the referenced application.

I. Status of Claims

The status indicated in the Examiner Answer and Appeal Brief remain correct: Claims 55-103 are pending and stand finally rejected as set forth in the Office Action mailed February 15, 2008 ("Final Office Action"). Claims 1-54 are canceled. The rejections of claims 55-103 are being appealed.

II. Grounds of Rejection to Be Reviewed On Appeal

The following grounds of rejection are presented for review:

Ground No. 1

Whether the description in the specification of the subject matter of claims 58 and 61 satisfies the enablement requirement of 35 U.S.C. § 112, first paragraph.

The Examiner's Answer, at Part 6, indicates that the rejection of claims 58 and 61 over 35 U.S.C. § 112, first paragraph, has been withdrawn. Accordingly, this ground of rejection is no longer presented for review.

Ground No. 2

Whether a *prima facie* case of anticipation has been established to support a rejection of claims 77-84, 86-93, and 95-103 over U.S. Patent No. 5,366,454 to Currie et al. ("Currie")[1].

Ground No. 3

Whether a *prima facie* case of obviousness has been established to support a rejection of claims 55-76, 85, and 94 over Currie.

[1] Appellants note that the Examiner made a typographic error in rejecting claims 85 and 94 under 35 U.S.C. § 102(b) as anticipated by Currie. As explained in the Examiner's Answer, claims 85 and 94 instead are rejected under 35 U.S.C. § 103 as obvious over Currie. (See Examiner's Answer, Pg. 2, 8-9; Final Office Action, Pg. 3-4).

III. Argument

A. Ground No. 1

Because the rejection of claims 58 and 61 over 35 U.S.C. § 112, first paragraph, has been withdrawn, no additional argument is needed.

B. Ground No. 2

The rejection of claims 77-84, 86-93, and 95-103 over Currie is erroneous. A proper *prima facie* case of anticipation has not been established to support the rejection. The Examiner's Answer essentially recites the same rejections and arguments provided in the Final Office Action from which this Appeal is taken.

As described in the Appeal Brief, filed August 25, 2008, Appellants' claims are directed to devices having multiple, tiny, containment reservoirs that can be opened at a selected time by causing the disintegration of individual reservoir caps that cover the reservoirs' openings. The devices may be a medical device, such as an implantable medical device, for example, for the controlled delivery of drug molecules, or for use in medical diagnostics. The claimed devices require a substrate, at least two reservoirs in the substrate, and discrete reservoir caps positioned over, or within, or covering, the at least two reservoirs.

The Examiner erroneously maintains that "the reservoir caps are formed of materials that passively disintegrate, materials that allow the molecules to diffuse passively out of the reservoir over time, or materials that disintegrate upon application of an electric potential." (Examiner's Answer, Pg. 7). Instead, all of Appellants' claims recite only reservoir caps that are **selectively disintegrable**. Claims 55-76 require discrete metal or electrically conductive reservoir caps, wherein release of the drug molecules from the device is activated by disintegration of the

reservoir cap. Claims 77-103 require control circuitry for selectively disintegrating the reservoir caps to open the reservoirs.

Currie does not describe a reservoir cap that is selectively disintegrable. Instead, Currie discloses only a rupturable membrane, formed of silicon, having a predetermined elastic deformation limit and a predetermined rupture point that seals the delivery opening of each compartment. (Currie, Col. 1, Lns. 54-58, 64-67). Attached to the rupturable membrane is a rupturing system, such as a piezoelectric transducer, that mechanically deforms upon application of a voltage between certain faces of the material. (Currie, Col. 1, Ln. 67 – Col. 2, Ln. 8). Upon application of the voltage, the mechanical deformation of the piezoelectric transformer applies sufficient stress to the rupturable membrane to cause the membrane to rupture. (Currie, Col. 2, Lns. 5-13). This mechanism is very different than the selective disintegration described and claimed by Appellants.

The Examiner insists that the "'rupturing' of Currie's cap 24 equates to the 'disintegrating' as claimed by applicant." (Examiner's Answer, Pg. 8). This is absolutely incorrect. The rupturing in Currie is purely mechanical, and Currie even provides a polymeric film to trap the shards of ruptured membrane. (Currie, Col. 6, Ln. 67 – Col. 7, Ln. 3). In contrast, Appellants' claimed invention recites "disintegrating the reservoir caps." An example of reservoir cap disintegration includes dissolution into solution, or formation of soluble ions or oxidation compounds, upon application of an electric potential generated by control circuitry. Appellants' mechanism of molecular scale disintegration, such as a phase change or chemical reaction, is different from the macroscale, mechanical fragmentation of Currie's rupture mechanism.

Even the Examiner's own dictionary definition reveals the difference between disintegration and rupturing. The Examiner maintains that "disintegration includes the condition of being decayed; breakdown, decomposition (see www.answers.com). Similarly, 'rupture' means that the process or instance of breaking open or bursting, or the state of being broken open." (Examiner's Answer, Pg. 8). Decay, breakdown, and decomposition are very different from breaking open and bursting. Appellant's mechanism of disintegration is at the molecular scale whereas Currie's mechanism is at the macroscale. Appellant's reservoir caps disintegrate, leaving no shards or fragments behind, whereas the reservoir caps described by Currie burst open, leaving behind shards or fragments. Currie even provides a polymeric film to trap the shards of ruptured membrane. (Currie, Col. 6, Ln. 67 – Col. 7, Ln. 3). The Examiner's very own definitions reveal differences between disintegration and rupturing of the reservoir cap.

Appellants' mechanism of molecular scale disintegration, such as a phase change or chemical reaction, is different from the macroscale, mechanical fragmentation of Currie's rupture mechanism. Since Currie fails to disclose Appellants' claimed feature of disintegrating the reservoir caps, the claims are not anticipated.

Claims 97 and 98 are novel over Currie.

Claims 97 and 98 expressly require that the reservoir cap disintegration include "dissolving into solution, or forming soluble ions or oxidation compounds upon application of an electrical potential generated by the control circuitry." The Examiner inexplicably maintains that Currie's disclosure of the mixing of the medicine contained in the compartments with bodily fluids is a disclosure of the specific reservoir cap disintegration required by claims 97 and 98. Currie discloses the dissolution of the reservoir contents with bodily fluids; it does not

disclose the dissolution of the reservoir cap covering the compartment. In fact, nothing in Currie mentions dissolution or oxidation being part of the membrane rupturing mechanism, and nothing in Currie teaches a rupturing mechanism that involves dissolution or oxidation induced by application of an electric potential.

C. Ground No. 3

The rejection of claims 55-76, 85, and 94 over Currie is erroneous. A proper *prima facie* case of obviousness has not been established to support the rejection. Claims 55-76, 85, and 94 require disintegratable reservoir caps. Independent claim 55 and dependent claims 56-68 require "discrete metal reservoir caps." Independent claim 69 and dependent claims 70-76 require "electrically conductive reservoir caps." Dependent claims 85 and 94 require reservoir caps comprising a "metal film." Currie fails to teach or suggest disintegratable reservoir caps that are metal or electrically conductive.

As discussed above in Part B, Currie discloses a pre-stressed silicon membrane covering openings of a plurality of medicine-containing compartments. Currie also provides a piezoelectric transducer that mechanically deforms upon application of an electric potential. The mechanical deformation of the piezoelectric transducer applies additional stress to the pre-stressed, brittle silicon membrane, causing the membrane to rupture into fragments to release the drug. In contrast, Appellants' mechanism involves molecular scale disintegration, rather than macroscale mechanical rupture, of the reservoir cap. Appellants' reservoir cap disintegration includes dissolution into solution, or formation of soluble ions or oxidation compounds, upon application of an electric potential generated by control circuitry. This mechanism is in contrast to the mechanical rupture mechanism of Currie, which relies on the inherent brittleness or

fragility of the silicon membrane. Metal or electrically conductive material required by the claims generally are ductile, so one of ordinary skill in the art starting with Currie would have no reason to remove the thin, brittle silicon membrane and replace it with a metal reservoir cap. If one replaced the brittle silicon membrane with a metal reservoir cap, the reservoir cap would not rupture. Moreover, because the mechanism of Currie does not require the passage of electricity through the reservoir cap, one of ordinary skill in the art starting with Currie would have no reason to replace the silicon membrane with an electrically conductive material.

The Examiner's Answer provides little reasoning supporting the obviousness rejection. The Federal Circuit has made clear that "there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." In re Kahn, 441 F.3d 977, 988, 78 U.S.P.Q.2d 1329, 1336 (Fed. Cir. 2006). The Examiner's Answer fails to articulate with any clarity how Currie is alleged to render obvious the disintegratable reservoir caps of Appellants' claims. Because the Examiner has failed to explain some rational underpinning to support the obviousness conclusion, the Examiner has failed to establish a *prima facie* case of obviousness. Thus, the rejection must fail.

The Examiner specifically conceded at page 5 of the Office Action mailed August 24, 2007 that "Currie does not disclose the reservoir cap formed of metal." Instead, the Examiner's argument for obviousness centers around Currie's disclosure that its silicon membrane may be "anodically bonded" to the silicon body of the device. (Currie, Col. 5, Ln. 57-58). Thus, the Examiner maintains that "the silicon membrane can be used as an anode material." (Examiner's Answer, Pg. 9). The Examiner further reasons that because the silicon membrane may be used as an anode material, and because Appellant's metal reservoir cap may serve as an anode, it

allegedly would have been obvious to one of ordinary skill in the art to substitute silicon for metal or vice versa. (Id.)

The Examiner acknowledges that the Examiner must provide evidence that supports the assertion that a silicon reservoir cap may be substituted for a metal reservoir cap Instead of providing sound evidence and reasoning, however, the Examiner simply cites the same references that were cited in the Final Office Action from which this Appeal was taken. The Examiner reasons, as can be best understood by Appellants, that Currie's disclosure that the silicon membrane is anodically bonded to the silicon body means that the silicon membrane can be used as an anode material. (Examiner's Answer, Pg. 10-11; Final Office Action, Pg. 4). The Examiner cites U.S. Patent No. 6,537,938 to Miyazaki ("Miyazaki") as evidence that in anodic bonding silicon is used as an anode. (Examiner's Answer, Pg. 12; Final Office Action, Pg. 8). Further, since the silicon membrane allegedly can be used as an anode, and since Appellants disclose that the conductive metal reservoir caps serve as anodes, it allegedly would be obvious to substitute metal for the silicon membrane in Currie. Moreover, the Examiner reasons that since silicon and metal allegedly can serve as anode material in electrochemical cells, as evidenced by U.S. Patent No. 4,623,597 to Auborn ("Auborn") or U.S. Patent No. 4,623,597 to Sapru et al. ("Sapru"), it would be obvious to substitute metal for the silicon membrane in Currie. The Examiner further seeks to take official notice of this alleged "common knowledge in the art." (Examiner's Answer, Pg. 10). The Examiner's hindsight-driven analysis is both legally and factually incorrect.

First, the Examiner's hindsight-driven reasoning is legally insufficient. The Examiner relies upon Appellants' teaching that the conductive metal reservoir caps serve as anodes, and uses this teaching against the Appellants. This sort of hindsight reasoning is prohibited.

Appellants' disclosure is not part of the prior art. Thus, Appellants' disclosure of conductive metal anodes cannot be used as a motivation for searching in the prior art for piecemeal elements from the wholly unrelated, non-analogous area of batteries to use against them. Thus, the rejection is legally improper and insufficient. The Examiner's Answer does nothing to correct this deficiency.

Second, the Examiner's reasoning is factually incorrect. Currie's disclosure of anodic bonding simply does not mean that the silicon membrane "can be used as an anode material." Currie makes clear that the silicon membrane is joined with the silicon body of the device using anodic bonding, so that the "membrane is integral with the body." (Currie, Col. 5, Ln. 53-58). Currie does not use anodic bonding as a mechanism for rupturing the silicon membrane. Anodic bonding is understood in the art of microfabrication to refer to a specific method of bonding two materials together—not for selectively disintegrating a material. As described in the Appeal Brief, anodic bonding of silicon to silicon wafer utilizes Pyrex glass as an intermediary and requires a negative cathode coupled to the Pyrex glass and a positive anode coupled to a first silicon wafer. A large voltage is applied between the electrodes to create migration of sodium cations in the glass towards the cathode, leaving a negative charge at the interface, which, as the electrons from the silicon wafer are drawn to the anode, attracts the silicon cations from the silicon wafer to form a strong SiO_2 interface to bond the silicon wafer to the glass. By bonding another silicon wafer to the opposite side of the Pyrex glass interlayer in the same manner, the two silicon wafers are joined together. (Appeal Brief, Pg. 15, Appendix 2).

In addition, the Examiner's reasoning is factually incorrect because neither Auborn nor Sapru provide evidence that the silicon membrane disclosed in Currie can be used as an anode material. In seeking to take official notice that silicon may be substituted for metal as an anode

material, the Examiner misinterprets Auborn and Sapru. Auborn discloses as an anode a metal and silicon alloy—not silicon alone. Sapru discloses an anode comprising a disordered multicomponent material formed of a host matrix element, which may be silicon, and modifier elements. Thus, both Auborn and Sapru disclose anodes requiring silicon and another material, whereas Currie discloses a membrane comprising only silicon. One of ordinary skill in the art would not read Currie, alone or in combination with another reference, to disclose a silicon membrane that can function as an anode.

Furthermore, the Examiner incorrectly cites Miyazaki as evidence that in anodic bonding silicon is used as an anode. As described in the Appeal Brief, one of ordinary skill in the art reading Miyazaki as a whole would not read the reference to disclose the use of silicon as an anode. The portion cited in the Examiner's Answer is contrary to the remainder of the reference and the knowledge in the art. In the portion relied upon by the Examiner, Miyazaki contradicts himself by first stating that the glass is used as a cathode and then by stating that cations in the glass move to the cathode. (Miyazaki, Col. 1, Lns. 32-34). At column 4, line 65 to column 5, line 2, Miyazaki describes and illustrates separate electrodes to anodically bond silicon and glass. One of ordinary skill in the art reading Miyazaki would understand that in anodic bonding the silicon and glass are not used as electrodes, but rather a separate anode and cathode are required for anodic bonding to occur. The disclosure of Currie, read alone or in combination with Miyazaki, does not, under any interpretation by one of ordinary skill in the art, mean that the silicon membrane can be used as an anode material.

Currie fails to teach or suggest the claimed combination of elements defining Appellants' claimed devices. One of ordinary skill in the art would not have substituted a metal or electrically conductive material for the brittle, silicon membrane disclosed by Currie.

Furthermore, the Examiner fails to establish a prima facie case of obviousness based on the prior art. The rejection of claims 55-76, 85, and 94 over Currie is erroneous and should be reversed.

In conclusion, the cited prior art, as a whole, fails to teach the claimed combination of elements defining Appellants' claimed devices and methods. No *prima facie* case of anticipation or obviousness has been established based on the references of record, alone or in combination. Appellants respectfully request that the Board reverse the Examiner and order the allowance of all claims.

Respectfully Submitted,

/Kevin W. King/
By: Kevin W. King
Reg. No. 42,737

Date: January 11, 2009

SUTHERLAND ASBILL & BRENNAN LLP
999 Peachtree Street, NE
Atlanta, Georgia 30309-3996
Telephone: 404.853.8068
Facsimile: 404.853.8806